



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

February 3, 1999

**WARNING LETTER NYK 1999-29**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

William J. Reilly, Owner  
Elmira Seafood  
456 W. Washington Avenue  
Elmira, NY 14901

Dear Mr. Reilly:

An inspection of your facility was performed September 2 & 8, 1998 by U.S. Food and Drug Administration (FDA) Investigator Steven J. Libal. The inspection revealed tuna, processed at and distributed from your facility, is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. It is adulterated because your firm failed to operate in accordance with the requirements of Title 21, Code of Federal Regulations (21 CFR) Part 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products".

As we explained in a previous letter to your firm, these regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of fresh tuna deviates from the regulations contained in 21 CFR 123 as follows:

- Failure to maintain sanitation control records that document the monitoring of all appropriate conditions and practices during processing with sufficient frequency to ensure proper sanitation [21 CFR 123.11(c)].

You should take prompt action to correct this violation at your firm. Failure to achieve prompt corrective action may result in further regulatory action - without further notice. These actions include seizure and/or injunction.

Elmira Seafood


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Additional deviations from 21 CFR 123 noted during our inspection, for which corrective action should be taken, include the following:

- Failure to perform timely record review of HACCP records, e.g., monitoring records of tuna upon receipt and monitoring records of storage temperature [21 CFR 123.8(a)(3)].
- Failure to maintain records of the calibration of process monitoring instruments [21 CFR 123.8(a)(2)(ii)].
- Failure to have a HACCP trained individual to review records [21 CFR 123.10].

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address. If you require further information, you may contact Mr. Kewley by telephone at (716) 551-4461 ext. 3128.

Sincerely,



Brenda J. Holman  
District Director